EPA–APPROVED REGULATIONS IN THE DELAWARE SIP

State citation	Title/subject	State effective date	EPA approval date	Comments
*	*	*	*	*
Regulation 39—Nitrogen Oxides (NO_X) Budget Trading Program				
Section 1	Purpose	12/11/00	5/17/01 Federal Register cite.	[Use this section as necessary to explain exceptions or limitations]
Section 2	Emission Limitation	12/11/00		
Section 3	Applicability	12/11/00		
Section 4	Definitions	12/11/00		
Section 5	General Provisions	12/11/00		
Section 6	NO_X Authorized Account Representative for NO_X Budget Sources.	12/11/00		
Section 7	Permits	12/11/00		
Section 8	Monitoring and Reporting	12/11/00		
Section 9	NATS	12/11/00		
Section 10	NO_X Allowance Transfers	12/11/00		
Section 11	Compliance Certification	12/11/00		
Section 12	End-of-Season Reconciliation	12/11/00		
Section 13	Failure to Meet Compliance Requirements.	12/11/00		
Section 14	Individual Unit Opt-Ins	12/11/00		
Section 15	General Accounts	12/11/00		
Appendix ''A''	Allowance Allocations to NO_X Budget Units.	12/11/00		
Appendix ''B''	Regulation No. 37—Regulation No. 39 Program Transition.	12/11/00		
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301126; FRL–6781–8]

RIN 2070–AB78

Cyfluthrin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of cyfluthrin in or on grapes and raisins; grain of barley, oats, and wheat; and fat of cattle, goats, hogs, horses and sheep. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on grapes and stored grain. This regulation establishes maximum permissible levels for residues of cyfluthrin in these food commodities. These tolerances will expire and are revoked on June 30, 2003.

DATES: This regulation is effective May 17, 2001. Objections and requests for hearings, identified by docket control number OPP–301126, must be received by EPA on or before July 16, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301126 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Stephen Schaible, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703–308–9362; and e-mail address: schaible.stephen@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that

might be available electronically,from the EPA Internet Home Page at http://www.epa.gov. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the**Federal Register** listings at http://www.epa.gov/fedrgstr/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_180/Title_40/40cfr180_00.html, a beta site currently under development.

2.*In person*. The Agency has established an official record for this action under docket control number OPP–301126. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing tolerances for residues of the insecticide cyfluthrin, cyano[4-fluoro-3-phenoxyphenyl]-methyl-3-[2,2-dichloroethenyl]-2,2-dimethyl-cyclopropanecarboxylate, in or on grape at 1.0 part per million (ppm); grape, raisin at 1.5 ppm; grain of barley, oats, and wheat at 2.0 ppm; and fat of cattle, goats, hogs, horses and sheep at 6.0 ppm. These tolerances will expire and are revoked on June 30, 2003. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Section 408(e) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by the Food Quality Protection Act (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemptions for Cyfluthrin on Grapes and Stored Grains and FFDCA Tolerances

According to the South Dakota Department of Agriculture, reports of damage to stored grain from infestations of lesser grain borer have increased in recent years. Lesser grain borer is a serious pest of stored grain because it is capable of destroying whole, sound grain. Storage of grain in larger, less protective structures have caused grain to be more vulnerable to infestations, primarily because the grain remains warmer, creating conditions favorable to insect development. The Applicant claims that there are not currently any effective registered alternatives for control of lesser grain borer. Reldan 4E (chlorpyrifos-methyl) is registered for use on wheat and sorghum but will not control lesser grain borer. Most malathion uses are no longer available, but even if they were insect resistance has built up to the point that this chemical is not effective. Phosphine gas is the primary fumigant of stored grain, but lesser grain borer has begun to demonstrate resistance. Storcide is a combination product containing the active ingredients chlorpyrifos-methyl and cyfluthrin; while the chlorpyrifos-methyl component of this product controls most insect pests in stored grain, the cyfluthrin component is necessary to control the lesser grain borer. The Applicant predicts that without the proposed use of Storcide, between 33% and 50% of bushels could be affected, resulting in $13.3 million in economic losses.

The California Department of Pesticide Regulation states that glassy winged sharpshooters are a recently introduced pest of grape production, and serve as a vector of Pierce's disease, which is caused by the bacterium *Xylella fastidiosa*. This disease can destroy a vineyard within 12 months and can still kill vines 2 to 3 years after infection. Since 1998, growers have observed a 25–30% reduction in vines, with 80% of some vineyard blocks being removed due to the disease. This same infection process and bacterium are the causal agents for other plant diseases in peaches in the southeastern United States and citrus in Brazil.

The required feeding time necessary for the pest to successfully vector bacterium for Pierce's disease is not known as of yet. Therefore, rapid control of the glassy winged sharpshooter may be essential to avoid significant economic losses. Given this, the Applicant claims that the available alternatives, imidacloprid and dimethoate, are not sufficient to provide control of this pest throughout the 7–month period of occurrence in California vineyards. While imidacloprid may provide some control of this pest, the soil applied formulation is slow acting and the foliar formulation has little persistence (thus making multiple applications necessary). The pre-harvest interval for dimethoate makes it impractical for use in grapes. Because of its rapid population advance

and ability to vector problem plant diseases, glassy-winged sharpshooter is now considered to be a significant threat to California's $2.8 billion/year wine, raisin, table grape and citrus industries. The California Department of Food and Agriculture (CDFA) maintains that Pierce's disease is responsible for $12 million in losses of grapevines in Temecula, California.

EPA has authorized under FIFRA section 18 the uses of cyfluthrin on grapes for control of glassy winged sharpshooter in California and on stored grain in South Dakota for control of lesser grain borer and other insect pests. After having reviewed these submissions, EPA concurs that emergency conditions exist for these States.

As part of its assessment of these emergency exemptions, EPA assessed the potential risks presented by residues of cyfluthrin in or on grapes, raisins, and grain, and by secondary residues of cyfluthrin in animal commodities as a result of treated grain commodities being used as feed items. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemptions in order to address urgent non-routine situations and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in section 408(l)(6). Although these tolerances will expire and are revoked on June 30, 2003, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on grapes and raisins; grain of barley, oats, and wheat; and fat of cattle, goats, hogs, horses and sheep after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed the levels that were authorized by these tolerances at the time of those applications. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether cyfluthrin meets EPA's registration requirements for use on grapes or stored grain or whether permanent tolerances for these uses would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of cyfluthrin by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than California or South Dakota to use this pesticide on these crops under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemptions for cyfluthrin, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7) .

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of cyfluthrin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for residues of cyfluthrin in or on grape at 1.0 ppm; grape, raisin at 1.5 ppm; grain of barley, oats and wheat at 2.0 ppm; and fat of cattle, goat, hogs, horses and sheep at 6.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances follows.

A. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological endpoint. However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for cyfluthrin used for human risk assessment is shown in the following Table 1:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR CYFLUTHRIN FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose (mg/kg bwt/day)	Endpoint	Study
Acute Dietary (All population)	Developmental NOAEL = 20.0; LOAEL = 60.0	Increased numbers of resorption and percent incidence of postimplantation loss in rabbits in a developmental toxicity study.	Developmental - rabbit (oral)
	UF=300 (10x inter- and 10x intra- and 3x FQPA considerations)	Acute Population Adjusted Dose (aPAD)aPAD = NOAEL/UF= 20/300 = 0.07 mg/kg bwt/day	
Chronic Dietary	NOAEL = 2.5; LOAEL = 6.2	Decreased body weight gain in males, and inflammatory foci in kidneys of female rats in a chronic toxicity/ carcinogenicity study.	2-year rat (oral)
	UF = 300: 10X inter- and 10X intra and 3x FQPA factor for all population subgroups	Chronic Population Adjusted Dose (cPAD) cPAD = NOAEL/UF = 2.5/300 = 0.008 mg/kg bwt/day	
Short, intermediate-Term (1–7 days) Occupational/Residential	Dermal NOAEL =20.0; LOAEL =60.0 (Dermal absorption rate = 25%)	Increased numbers of resorption and percent incidence of postimplantation loss in rabbits.	Developmental - rabbit (oral)
		MOE = 300	
Intermediate-Term (one week to several months) Occupational/ Residential	Dermal NOAEL = 20.0; LOAEL = 60.0 (Dermal absorption rate = 25%)	Increased numbers of resorption and percent incidence of postimplantation loss in rabbits. MOE = 300	Developmental - rabbit (oral)
Long-Term	Dermal NOAEL = 2.5; NOAEL = 6.2 (Systemic) Dermal absorption rate = 25%	Decreased body weight in male and inflammatory foci in the kidney of female rats in a chronic toxicity/ carcinogenicity study. MOE=300	2–year rat (oral)
All time periods	Inhalation: Short-Term: NOAEL = 0.44 μg/L = 0.12 mg/kg/day;LOAEL=6 μg/L	Decreases in body and thymus weights, hypothermia and clinical pathology in rats in a 28–day study (short-term) and behavioral effects in rats in a 90–day study (intermediate/ chronic). UF = 300	28–day rat inhalation study (short-term)
	Intermediate/Chronic: NOAEL = 0.09 μg/L = 0.024 mg/kg/ day;LOAEL=0.7 μg/L	The extrapolation method was used in converting the NOAEL from μg/L to mg/kg/day	90-day rat inhalation study (intermediate/chronic)
Cancer	Oral	Cyfluthrin is classified as a group E chemical. Carcinogenicity studies in rats and mice were negative.	

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.436) for the residues of cyfluthrin, in or on a variety of raw agricultural commodities. Existing tolerances for aspirated grain fractions (300 ppm), sorghum, grain (4 ppm); and meat and meat byproducts of cattle, goats, hogs, horses, and sheep (0.4 ppm for both meat and meat byproducts) are sufficient to cover residues resulting from the application of cyfluthrin under the emergency

exemption. The existing tolerance of 5.0 ppm for fat of cattle, goats, hogs, horses, and sheep is insufficient to cover residues resulting from section 18 use on stored grains; the time-limited tolerance of 6.0 ppm is therefore being established. While time-limited tolerances of 1.0 ppm for grapes and 1.5 ppm for raisins are required, no concentration of residues occurs in grape juice and a separate tolerance for that commodity is not required. For purposes of dietary risk assessment, residue data generated from residue field trials conducted at maximum application rate and minimum preharvest intervals were used, as were processing data for grapes. To assess secondary exposure from edible animal commodities, animal dietary burdens were calculated using mean field trial residues, adjusted to take into account percent of crop treated information, and applying appropriate processing factors for all feed items. Risk assessments were conducted by EPA to assess dietary exposures from cyfluthrin in food as follows:

i. *Acute exposure*. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: anticipated residues and percent of crop treated refinements were used for existing tolerances; anticipated residues and 100% of crop treated were assumed for the proposed tolerances associated with section 18 uses on stored grains and grapes. Anticipated residues were also assumed for meat, milk, poultry and egg tolerances. This Tier 3 Monte Carlo analysis is considered partially to highly refined. Field trial residue distributions were assumed for those foods identified by EPA as single-serving commodities. For those foods considered to be blended or processed, mean field trial residues were calculated, substituting the full limit of detection (LOD) for those samples for which residues were reported below the LOD.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: field trial residues and percent of crop treated refinements were used for the existing tolerances; anticipated residues and 100% of crop treated were assumed for the section 18 uses on stored grains and grapes. Anticipated residues were also assumed for meat, milk, poultry and egg tolerances. This Tier 3 analysis is considered partially to highly refined.

iii. *Cancer*. Cyfluthrin has been classified as a not likely human carcinogen (Group E chemical). A cancer dietary risk assessment is not required.

iv. *Anticipated residue and percent crop treated information*. Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a data call-in for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; Condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and Condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of percent crop treated (PCT) as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used percent crop treated (PCT) information as shown in the following Table 2:

TABLE 2.—PERCENT OF CROP TREATED ESTIMATES FOR ACUTE AND CHRONIC RISK ASSESSMENT

Site	Percent of Crop Treated	
	Weighted Average (Chronic)	Estimated Maximum (Acute)
Corn	1	3
Alfalfa	1	1
Orange	5	13
Sorghum	1	1
Sweet Corn	3	6
Tomato	3	5

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the

data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which cyfluthrin may be applied in a particular area.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for cyfluthrin in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of cyfluthrin. Cyfluthrin is poorly mobile and moderately persistent, and will remain sorbed to the soil for weeks following treatment. This suggests little potential to leach and contaminate groundwater, but high potential for transport to surface water via particulate run-off during rain events.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/ Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/ EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to cyfluthrin they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of cyfluthrin for acute exposures are estimated to be 5.49 parts per billion (ppb) for surface water and 0.006 ppb for ground water. The EECs for chronic exposures are estimated to be 2.18 ppb for surface water and 0.006 ppb for ground water. Because the Tier II PRZM/EXAMS exposure estimates exceed the solubility of cyfluthrin in water, EPA used the value of 1.2 ppb, the solubility of cyfluthrin in water, as the acute and chronic EEC for the surface water drinking water assessment. This value represents that maximum concentration of cyfluthrin that would be found in surface water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Cyfluthrin is currently registered for use on the following residential non-dietary sites: residential lawn and gardens, inside households, carpets, and as a termiticide. The termite control is achieved by establishing a continuous chemical barrier between the wood and the termite colonies in the soil. Like many other termite control chemicals, cyfluthrin is normally applied to the entire surface of soil or other substrate to be covered by the slab before the construction, or applied under the slab after the construction. The potential of dermal exposure is not expected. However, some termite control chemicals applied to the soil may penetrate house foundation to become a source for emission inside of the house. Consequently, short-term and intermediate-term as well as chronic exposures via inhalation route may occur. However, the vapor pressure of cyfluthrin is 3.3×10 E-8 Torr which indicates that the amount of emission from this chemical is extremely limited. For this reason, the potential of inhalation exposure is also very limited. Based on these considerations, residential risk assessment was not conducted for the termiticide use.

As mentioned above, cyfluthrin is also registered for use on residential lawns and carpets (fogger). Under current Office of Pesticide Programs' (OPP) guidelines, these uses do not present a chronic exposure scenario; because exposure to cyfluthrin may occur as a result of inhalation or contact from indoor and outdoor uses, these uses do constitute a short- and/or intermediate-term exposure scenario. A residential exposure assessment for those uses of cyfluthrin was conducted in conjunction with the EPA's risk assessment supporting the extension of tolerances for synthetic pyrethroids. The exposure data (in mg/kg/day) from this assessment are summarized in the following tables 3 and 4:

TABLE 3.—EXPOSURE ASSESSMENT DATA FROM CYFLUTHRIN USE ON LAWNS

Scenario	Individual	Inhalation	Dermal	Oral
Lawn Application	Adult	not conducted	not conducted	not conducted
Post-Application Lawn	Adult	1.16E-05	1.39E-03	not conducted
Post-Application Lawn	Child (1–6)	2.78E-05	2.63E-03	2.85E-04
Post-Application Lawn	Infant (<1)	3.56E-05	2.72E-03	3.03E-04

This product for lawns is a restricted use pesticide, and therefore, required to be applied by professional lawn care operators only. Thus, from the applicator perspective, this lawn scenario is considered out of EPA's

scope for purposes of residential exposure.

TABLE 4.—EXPOSURE ASSESSMENT DATA FROM CYFLUTHRIN USE ON CARPET

Scenario	Individual	Inhalation	Dermal	Oral
Carpet (fogger) Application	Adult	not conducted	8.84E-03	not conducted
Post-Application Carpet	Adult	3.40E-05	1.63E-03	not conducted
Post-Application Carpet	Child (1-6)	8.56E-06	4.20E-03	3.60E-04
Post-Application Carpet	Infant (<1)	1.04E-05	4.65E-03	3.84E-04

4. *Cumulative exposure to substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether cyfluthrin has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, cyfluthrin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that cyfluthrin has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

C. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—-i. *In general*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Developmental toxicity studies*. In the rat developmental study, neither a maternal LOAEL nor a developmental LOAEL was observed. The maternal NOAEL was >10 mg/kg/day (the highest dose tested), as was the developmental NOAEL. The previously conducted range finding study supported the dose selection which was used in the developmental study, and the rat study is classified as an Acceptable guideline. In the rabbit developmental study, the maternal LOAEL was 60 mg/kg/day, based on decreased body weight gain and food consumption during the dosing period. The maternal NOAEL was 20 mg/kg/day. The developmental LOAEL was 60 mg/kg/day, based on increased numbers of resorptions and percent incidence of postimplantation loss. The developmental NOAEL is 20 mg/kg/day.

Two rat developmental toxicity studies via the inhalation route of exposure were also conducted. In the first study, maternal effects were observed at 4.7 mg/M^3 and above, and effects in the pups were observed at 1.1 mg/M^3 and above. At 1.1 mg/M^3 and above, a dose-related increase in the incidence of runts and skeletal anomalies in the sternum were observed. At 4.7 mg/M^3 and above, increases in post-implantation losses and decreases in pup weights were observed. At 23.7 mg/M^3, increased incidences of late embryonic deaths and in skeletal anomalies in the extremities, pelvis and skull were observed as well as microphthalmia. The maternal NOAEL is 1.1 mg/M^3 and the maternal LOAEL is 4.7 mg/M^3, based on reduced motility, dyspnea, piloerection, ungroomed coats and eye irritation. The developmental NOAEL is 0.59 mg/M^3 and the developmental LOAEL is 1.1 mg/M^3, based on increases in the incidence of runts and skeletal anomalies in the sternum (1.1 mg/M^3 and above), increases in post-implantation losses and decreases in pup weights (4.7 mg/M^3 and above), and increased incidences of late embryonic deaths, in skeletal anomalies in the extremities, pelvis and skull and in microphthalmia (23.7 mg/M^3).

In the second study, the maternal NOAEL and LOAEL were < 0.46 mg/M^3, based on decreased body weight gain and reduced relative food efficiency. The developmental NOAEL was 0.46 mg/M^3 and the developmental LOAEL was 2.55 mg/M^3, based on reduced fetal and placental weight, and reduced ossification in the phalanx, metacarpals, and vertebrae.

iii. *Reproductive toxicity study*. In the 3-generation rat reproduction study, the LOAEL for parental toxicity was 22.5 mg/kg/day, based on decreased body weight gains; the NOAEL was 7.5 mg/kg/day. The LOAEL for reproductive toxicity was 7.5 mg/kg/day based on decreased viability and lactational indices and decreased pup body weight gains. The NOAEL was 2.5 mg/kg/day.

iv. *Prenatal and postnatal sensitivity*. There are no data gaps for reproductive and developmental toxicity studies. Evidence of increased sensitivity of young rats following pre- and/or post-natal exposure to cyfluthrin was observed in the three-generation reproduction study in rats. There was suggestive sensitivity of rats to *in utero* exposure based on bradypnea seen in dams in the developmental inhalation studies. In addition, the reproductive NOAEL of 2.5 mg/kg/day and the LOAEL of 7.5 mg/kg/day established in the three-generation reproduction study in rats are identical to the systemic NOAEL/LOAEL of 2.5/7.5 mg/kg/day established in the chronic toxicity/carcinogenicity study in rats. This NOAEL (2.5 mg/kg/day) and a UF of 100 was used in deriving the RfD (0.025 mg/kg/day) and the RfD does not provide protection for infants and children.

v. *Conclusion*. There is a complete toxicity database for cyfluthrin and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Based on the considerations above, EPA determined that the tenfold FQPA safety factor should be replaced with an uncertainty factor of three for acute,

short- and intermediate-term, and chronic risk assessments. While evidence of increased sensitivity of young rats following pre- and/or post-natal exposure to cyfluthrin was observed in the three-generation reproduction study in rats, an uncertainty factor of 3 was selected because of the lack of severity of effects (reduced body weight gain in males in chronic toxicity study and decreased body weight gain in parental animals in the reproduction study) and the availability of acceptable reproduction (rat) and developmental (rats and rabbits) toxicity studies.

D. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to cyfluthrin in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of cyfluthrin on drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food to cyfluthrin at the 99.9th percentile will occupy 59% of the aPAD for the U.S. population, 28% of the aPAD for females age 13–50 years, 89% of the aPAD for infants and 80% of the aPAD for children aged 1 through 6 years. In addition, despite the potential for acute dietary exposure to cyfluthrin in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of cyfluthrin in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 5:

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO CYFLUTHRIN

Population Subgroup	aPAD (mg/kg/day)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. population	0.07	59	1.2	0.006	1,000
All infants < 1 yr.	0.07	89	1.2	0.006	1500
Children 1–6 yrs.	0.07	80	1.2	0.006	140
Female 13–50 yrs.	0.07	28	1.2	0.006	80

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to cyfluthrin from food will utilize 30% of the cPAD for the U.S. population, 26% of the cPAD for infants < 1 yr. and 73% of the cPAD for children 1 through 6 years. Based on the use pattern, chronic residential exposure to residues of cyfluthrin is not expected. In addition, despite the potential for chronic dietary exposure to cyfluthrin in drinking water, after calculating DWLOCs and comparing them to conservative model estimated environmental concentrations of cyfluthrin in surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 6:

TABLE 6.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CYFLUTHRIN

Population Subgroup	cPAD mg/kg/day	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.008	30	1.2	0.006	200
All infants < 1 yr.	0.008	26	1.2	0.006	79
Children 1–6 yrs.	0.008	73	1.2	0.006	22

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Cyfluthrin is currently registered for uses that could result in short-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for cyfluthrin.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 1,500 for adults, 1,400 for children 1 through 6 years old, and 1,600 for infants < 1 year old. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, short-term DWLOCs were calculated and compared to the EECs for chronic exposure of cyfluthrin in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect short-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 7:

TABLE 7.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO CYFLUTHRIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
Adult (male)	1,500	300	1.2	0.006	1,900
Adult (female)	1,500	300	1.2	0.006	1,600
Child 1–6 yrs.	1,400	300	1.2	0.006	530
Infant < 1 yr.	1,600	300	1.2	0.006	540

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level).

Cyfluthrin is currently registered for use(s) that could result in intermediate-term residential exposure and the Agency has determined that it is appropriate to aggregate chronic food and water and intermediate-term exposures for cyfluthrin.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that food and residential exposures aggregated result in aggregate MOEs of 460 for adults, 530 for children 1 through 6, and 470 for infants < 1 year. These aggregate MOEs do not exceed the Agency's level of concern for aggregate exposure to food and residential uses. In addition, intermediate-term DWLOCs were calculated and compared to the EECs for chronic exposure of cyfluthrin in ground water and surface water. After calculating DWLOCs and comparing them to the EECs for surface and ground water, EPA does not expect intermediate-term aggregate exposure to exceed the Agency's level of concern, as shown in the following Table 8:

TABLE 8.— AGGREGATE RISK ASSESSMENT FOR INTERMEDIATE-TERM EXPOSURE TO CYFLUTHRIN

Population Subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Intermediate-Term DWLOC (ppb)
Adult (male)	460	300	1.2	0.006	800
Adult (female)	460	300	1.2	0.006	690
Children 1–6 yrs.	530	300	1.2	0.006	290
Infants < 1 yr.	470	300	1.2	0.006	240

5. *Aggregate cancer risk for U.S. population*. Cyfluthrin has been classified as a not likely human carcinogen (Group E chemical). A cancer dietary risk assessment is not required.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to cyfluthrin residues.

V. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas/liquid chromatography with an electron capture detector) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no Codex tolerances established for cyfluthrin on grapes, raisins, or grains. Nor have any tolerances been established by Canada or Mexico for cyfluthrin on grapes, raisins, or grains (of barley, oat, or wheat).

VI. Conclusion

Therefore, the tolerances are established for residues of cyfluthrin, cyano[4-fluoro-3-phenoxyphenyl]-methyl-3-[2,2-dichloroethenyl]-2,2-

dimethyl-cyclopropanecarboxylate, in or on grape at 1.0 ppm; grape, raisin at 1.5 ppm; grain of barley, oat, and wheat at 2.0 ppm; and fat of cattle, goat, hog, horse, and sheep at 6.0 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301126 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before July 16, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3.*Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VII.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by the docket control number OPP–301126, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VIII. Regulatory Assessment Requirements

This final rule establishes time limited tolerances under FFDCA section 408. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low- Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a FIFRA section 18 exemption under FFDCA section 408, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the

Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.''

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 3, 2001.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.436 is amended by adding paragraph (b) to read as follows:

§ 180.436 Cyfluthrin; tolerances for residues.

* * * * *

(b)*Section 18 emergency exemptions.* Time-limited tolerances are established for residues of the insecticide cyfluthrin, cyano[4-fluoro-3-phenoxyphenyl]-methyl-3-[2,2-dichloroethenyl]-2,2-dimethyl-cyclopropanecarboxylate in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. These tolerances will expire and are revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/revocation date
Barley, grain	2.0	6/30/03
Cattle, fat	6.0	6/30/03
Goat, fat	6.0	6/30/03
Grape	1.0	6/30/03
Grape, raisin	1.5	6/30/03
Hog, fat	6.0	6/30/03
Horse, fat	6.0	6/30/03
Oat, grain	2.0	6/30/03
Sheep, fat	6.0	6/30/03
Wheat, grain	2.0	6/30/03

* * * * *

[FR Doc. 01–12440 Filed 5–16–01; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF DEFENSE

Defense Logistics Agency

48 CFR Parts 5433 and 5452

DLA Acquisition Directive: Alternative Dispute Resolution

AGENCY: Defense Logistics Agency (DLA), Defense.

ACTION: Final rule.

SUMMARY: This final rule adds a new provision to DLA solicitations concerning the use of alternative dispute resolution (ADR). The purpose is to establish ADR as the initial dispute resolution method, except for certain circumstances, to increase cooperative problem solving and reduce litigation. The provision is optional for offerors; however, if they agree to the provision, both the contractor and DLA will be committed to use of ADR except in limited circumstances. Increased use of ADR is consistent with the Administrative Dispute Resolution Act, the Federal Acquisition Regulation (FAR), and Departmental policy.

EFFECTIVE DATE: May 17, 2001.

FOR FURTHER INFORMATION CONTACT: Ms. Mary Massaro, Procurement Analyst, Defense Logistics Agency, DLA/J–336, at (703) 767–1366, or via email to mary_massaro@hq.dla.mil.

SUPPLEMENTARY INFORMATION:

A. Background

DLA is pursuing several initiatives to increase the use of ADR in resolving contract disputes. One way to increase use of ADR is for the parties to agree, as part of the contract, that they will use ADR before initiating litigation. This type of approach is used by DoD in partnering agreements and Agency-contractor ADR pacts.

The provision provides a vehicle for both parties to agree to use ADR. Offerors can opt out of the provision by checking the box if they do not want it in their contract in the event of award. Offerors can also propose alternate wording to tailor the language while retaining the concept.

A proposed rule was published in the **Federal Register** on May 16, 2000. Sixteen commenters submitted comments. Changes were made to the proposed rule to clarify or simplify the language, and to reference existing FAR and DLA requirements. The language of the final rule, as revised, appears below.

B. Regulatory Flexibility Act

This final rule does not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq. An initial regulatory flexibility analysis was not performed.

C. Paperwork Reduction Act

This rule does not impose any new reporting or recordkeeping requirements that require the approval of OMB under 44 U.S.C. 3501 et seq.

List of Subjects in 48 CFR Parts 5433 and 5452

Government procurement.

For the reasons set forth above, the Defense Logistics Agency amends 48 CFR Chapter 54 as follows:

1. Part 5433 is added to read as follows:

PART 5433—PROTESTS, DISPUTES AND APPEALS

Authority: 10 U.S.C. Chapter 137.

5433.214. Alternative Dispute Resolution (ADR).

The contracting officer shall insert the provision in 5452.233 in all solicitations unless the conditions at FAR 33.203(b) apply.

PART 5452—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

2. The authority citation for Part 5452 continues to read as follows:

Authority: 10 U.S.C. Chapter 137.

3. Part 5452 is amended by adding solicitation provision 5452.233–9001 to read as follows:

5452.233–9001 Disputes: Agreement to Use Alternative Dispute Resolution (ADR).

As prescribed in 5433.214, insert the following provision:

Disputes: Agreement to Use Alternative Dispute Resolution (ADR) (Apr 2001)—DLAD

(a) The parties agree to negotiate with each other to try to resolve any disputes that may arise. If unassisted negotiations are unsuccessful, the parties will use alternative dispute resolution (ADR) techniques to try to resolve the dispute. Litigation will only be considered as a last resort when ADR is unsuccessful or has been documented by the party rejecting ADR to be inappropriate for resolving the dispute.

(b) Before either party determines ADR inappropriate, that party must discuss the use of ADR with the other party. The documentation rejecting ADR must be signed by an official authorized to bind the contractor (see FAR 52.233–1), or, for the Agency, by the contracting officer, and approved at a level above the contracting officer after consultation with the ADR Specialist and with legal counsel. Contractor personnel are also encouraged to include the ADR Specialist in their discussions with the contracting officer before determining ADR to be inappropriate.

(c) If you wish to opt out of this clause, check here [ ]. Alternate wording may be negotiated with the contracting officer.

William J. Kenny,

Executive Director, Logistics Policy and Acquisition Management.

[FR Doc. 01–12450 Filed 5–16–01; 8:45 am]

BILLING CODE 3620–01–M